



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/669,817	09/26/2000	Joseph R. Byrum	38-21(51469)B	5384

7590

06/06/2005

Lawrence M Lavin Jr
Patent Department E2NA
Monsanto Company
800 N Lindbergh Boulevard
St. Louis, MO 63167

EXAMINER

MEHTA, ASHWIN D

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

MAILED
JUN 06 2005
GROUP 1600

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/669,817
Filing Date: September 26, 2000
Appellant(s): BYRUM ET AL.

Thomas E. Holsten and David R. Marsh
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 10 March 2005

(1) *Real Party in Interest*

78

Art Unit: 1638

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(8) *Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) *Prior Art of Record*

No prior art is relied upon by the examiner in the rejection of the claims under appeal.

(10) *Grounds of Rejection*

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1, 2, and 10-15 on appeal stand rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial utility or a well-established utility.

Art Unit: 1638

The claims are drawn towards any substantially purified nucleic acid molecule that encodes any plant protein comprising a nucleic acid sequence from SEQ ID NO: 4, wherein said substantially purified nucleic acid molecule is greater than 60% free from other molecules present in a natural mixture; or wherein said plant protein is a rice protein; or a substantially purified nucleic acid molecule comprising a nucleic acid sequence from SEQ ID NO: 4 or complement thereof, wherein said substantially purified nucleic acid molecule is greater than 60% free from other molecules present in a natural mixture; or a substantially purified nucleic acid molecule consisting a nucleic acid sequence from SEQ ID NO: 4 or complement thereof, wherein said substantially purified nucleic acid molecule is greater than 60% free from other molecules present in a natural mixture; or a substantially purified nucleic acid molecule comprising a nucleic acid sequence having between 100% and 90% sequence identity with a nucleic acid sequence of SEQ ID NO: 4 or complement thereof, wherein said substantially purified nucleic acid molecule is greater than 60% free from other molecules present in a natural mixture.

The specification discloses 43,701 nucleic acid sequences that are EST nucleic acid molecules, including SEQ ID NO: 4 (page 16, lines 1-6, sequence listing). The nucleic acid sequences were derived from rice cDNA libraries (page 33, lines 4-7; Example 1, pages 84-87). The specification generally indicates that the disclosed ESTs can be used to acquire genes whose encoded proteins are involved in various plant processes (page 33, lines 4-26), or to acquire promoters or cis-regulatory elements, or to generally obtain nucleic acid molecules from other organisms (page 34, line 1 to page 35, line 10). No particular use is disclosed for any putative protein encoded by SEQ ID NO: 4.

Art Unit: 1638

The claimed nucleic acid molecule is not supported by a specific asserted utility because the disclosed use of the nucleic acid is generally applicable to any nucleic acid and therefore is not particular to the claimed molecule. Further, the claimed nucleic acid molecule is not supported by a substantially utility because the specification states only that the EST is useful as a probe or primer in isolating other unspecific genes or regulatory regions of genes. Once such a gene is isolated and the protein obtained, further basic research would need to be conducted to characterize it. A starting material that can only be used to produce a final product does not have a substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case none of the proteins or regulatory regions that are to be produced as final products resulting from processes involving the claimed nucleic acid molecules have asserted or identified specific and substantial utilities. Identifying and studying the properties of the protein itself or the mechanisms in which the protein or regulatory region is involved does not define a "real world" context of use. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility has not been assessed. Neither the specification as filed nor any art of record discloses or suggests any property or activity for SEQ ID NO: 4 such that another non-asserted utility would be well established for the compounds.

Appellant's Arguments and Examiner's Response

Appellants argue that specification teaches identifiable benefits for the claimed nucleic acid, for example the use in identifying the presence or absence of a polymorphism and use a marker (Appeal Brief, page 5, 2nd full paragraph to page 9, 1st full paragraph). However, the

Art Unit: 1638

specification does not teach what the presence or absence of the polymorphism signifies. The specification indicates that polymorphisms are useful to define genetic distances or physical distances between polymorphic traits (page 45, lines 10-11). However, the specification does not teach what these traits are. The specification does not associate the presence or absence of any polymorphism with any particular condition or state. The specification generally discusses how any of the disclosed ESTs in the sequence listing can be used to detect polymorphisms, and how to do so (page 38, line 11 to page 45, line 21). But it does not explain why SEQ ID NO: 4 particularly would be useful in detecting polymorphisms. Polymorphisms are natural variations within sequences which themselves may not have any meaningful use. Therefore, determining whether the claimed nucleic acids, or the nucleic acids detected by the claimed nucleic acids, have or do not have a polymorphism would require determining whether there was a polymorphism within such a sequence, and then determining how to use this information in a patentably meaningful way.

The Appellant also argues that many of the disclosed utilities, including the detection of polymorphism, are directly analogous to the utilities of a microscope (Appeal Brief, page 8, 1st full paragraph). This argument has been reviewed but is not convincing because the microscope provides information to the scientist that is automatically useful. For example, the microscope may be used for identification and differentiation between gram-positive and gram-negative bacteria. The differentiation of bacteria facilitates in the administration of proper antibiotics. For example, use of a microscope to determine whether Staph is present or whether Strep is present provides valuable information to the scientist and/or doctor for treating

Art Unit: 1638

patients. The instant invention, however, provides no information to this extent. If the scientist determines that SEQ ID NO: 4 is present, one skilled in the art does not know how to use this information. Thus, the identification of SEQ ID NO: 4 is not a substantial utility. Appellants also argue that the fact that a microscope can be used for learning products or processes does not lessen the fact that such tools have legal utility. Appellants also draw analogy to the use of a gas chromatograph to analyze the composition of a gas (Appeal Brief, page 8, 1st and 2nd full paragraphs). However, in the instant case the specification does not even identify the products or processes that SEQ ID NO: 4 can be used to study.

Appellants also argue that the claimed nucleic acid molecules can be used as probes for other molecules or as a source of primers, to isolate nucleic acid molecules of other plants and organisms (Appeal Brief, page 9, 1st full paragraph). However, the specification does not teach the substantial use of such nucleic acid molecules of the other organisms. The specification does not teach any property of SEQ ID NO: 4 or any phenotype that is affected by it. In the absence of this information, using the claimed nucleic acid molecules as probes would only lead to the isolation of other nucleic acid molecules that lack substantial utility.

Appellants also argue that the specification indicates that the claimed nucleic acid molecule can be used to initiate a chromosome walk, to isolate a promoter (Appeal Brief, paragraph bridging pages 9-10). Appellants argue that the Examiner's position, that utility is lacking because other nucleic acid molecules can be used for the same purpose, is wrong because there is no requirement of exclusive utility in patent law. Appellants cite the decision of *Carl Zeiss Stiftung v. Renshaw PLC* in support, for stating that an invention need not be the best or only way to accomplish a certain result (Appeal Brief, page 10, 1st full paragraph). However, the

Art Unit: 1638

Examiner has not stated that the invention needs to be the best or only way to accomplish a certain result. The specification does not teach what the certain result is for the utility of the instant invention. The specification does not provide any expectation of successfully using SEQ ID NO: 4 to isolate promoters. Appellants also argue that the Examiner's position indicates that a new golf club has no legal utility because other golf clubs can be used to hit golf balls (response, page 10, 1st full paragraph). However, not every utility will satisfy 35 U.S.C. 101, even if the utility is shared with other things. For example, the utility of using a transgenic mouse as snake food is neither specific nor substantial because all mice can have this function.

Appellants argue that it is incorrect that the use of the claimed nucleic acid molecule in a chromosome walk is not specific, because they provide a particularly appropriate and demonstrably useful starting point, and that a random nucleic acid does not provide an equally good starting point (Appeal Brief, paragraph bridging pages 10-11). However, the specification does not demonstrate how SEQ ID NO: 4 provides a particularly appropriate and useful starting point. There is no evidence or expectation that the claimed nucleic acid molecules would be effective at all in a chromosome walk to isolate a promoter.

Appellants argue that the claimed nucleic acid molecules provide immediate benefit to the public in their use in detecting the presence or absence of polymorphisms, in that polymorphisms enable a plant breeder to determine the distribution of a parental genetic material in the progeny of a cross (Appeal Brief, paragraph bridging pages 11-12). However, the utility of the claimed nucleic acid molecules for detecting polymorphisms is not a substantial utility, for the reasons discussed above. Further, any unique nucleic acid sequence can be used to follow plants in a breeding program. Appellants also argue that the utility of EST sequences is self-

Art Unit: 1638

evident from the growth of a multi-million dollar industry in the United States premised on their usefulness (Appeal Brief, page 12, 1st and 2nd paragraphs). However, Appellants have not provided any suggestion about which use of ESTs the industry is premised on. The specification only goes so far as to speculate how the ESTs can be useful. Further basic research is required, even in the EST industry, to determine the specific and substantial utility of SEQ ID NO: 4. The use of SEQ ID NO: 4 is not clear, disclosed, well-established, specific, or substantial. The U.S. Supreme Court in *Brenner v. Manson*, *Supreme Court of the U.S. 148 USPQ 689 (1966)* made it clear that to meet the utility requirement under 35 U.S.C. 101, an invention must be useful in its currently available form, by indicating, "This is not to say that we mean to disparage the importance of contributions to the fund of scientific information [383 U.S. 519, 536] short of the invention of something "useful," or that we are blind to the prospect that what now seems without "use" may tomorrow command the grateful attention of the public. But a patent is not a hunting license. It's not a reward for the search, but compensation for its successful conclusion." The instant application provides only a starting point for the hunt. It does not reach a conclusion.

Claims 1, 2, and 10-15 on appeal stand rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Further, SEQ ID NO: 4 is a partial cDNA sequence, does not encode a complete protein, and is not predictive of the remaining sequences of the complete cDNA. As the function of the

Art Unit: 1638

claimed nucleic acid molecule, or the protein it encodes, is not taught, one skilled in the art therefore would not know how to use it. Undue experimentation would be required by one skilled in the art to determine the remaining nucleotide sequences of the coding region that SEQ ID NO: 4 is a part of, and characterize the function of the encoded product. See Genentech, Inc. v. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that “the specification, not the knowledge of one skilled in the art” must supply the enabling aspects of the invention. Also see In re Bell, 26 USPQ2d 1529, 1532 (Fed. Cir. 1993) and In re Deuel, 34 USPQ2d, 1210 (Fed. Cir. 1995), which teach that the mere existence of a protein does not enable claims drawn to a nucleic acid encoding that protein. See also Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016 at 1021 and 1027, (Fed. Cir. 1991) at page 1027, where it is taught that the disclosure of a few gene sequences did not enable claims broadly drawn to any analog thereof. Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

Appellants’ Arguments and Examiner’s Response

Appellants argue that the rejection is erroneous and has been overcome by the arguments regarding utility because it is well-established law that the enablement requirement is met if the description enables any mode of making and using the invention (Appeal Brief, page 14, 1st full paragraph). However, the utility requirements of 35 U.S.C. 101 have not been met for the claimed invention, for the reasons discussed above. The specification therefore does not enable one skilled in the art in the use of the invention.

Art Unit: 1638

Appellants also argue that an analysis of the criteria presented by *In re Wands* supports their position. Appellants argue that, for the criterion of quantity of experimentation necessary, that the quantum of experimentation is reduced by the knowledge of conservative nucleotide substitutions, identification of active site, and conserved regulatory elements (Appeal Brief, paragraph bridging pages 14-15). However, the nucleotide sequence of the open reading frame to which SEQ ID NO: 4 belongs is unknown. It is not clear how, in the absence of that information, one cannot predict or identify an active site, or perform other assays. Appellants argue that sufficient guidance is provided by the disclosure, which sets forth nucleic acid molecules and method of use thereof in the production of transgenic cells and plants, and that the performance of well-known steps such as sequence alignment cannot create undue experimentation (Appeal Brief, paragraph bridging pages 14-15). However, in the absence of the effect that SEQ ID NO: 4 has on a plant or cell, one skilled in the art would not know how to use transgenic cells and plants comprising it. Further, a sequence alignment would not provide conclusive data regarding the remaining sequences of the open reading frame that comprises SEQ ID NO: 4.

Appellants argue, regarding amount of direction or guidance given, that the specification provides evidence of sequence identity, discloses the identification of promoter regions associated with the claimed nucleic acid molecule, and discusses use of the claimed nucleic acid molecule to isolate additional sequences within a genome (Appeal Brief, page 15, 1st full paragraph). However, contrary to Appellants' assertion, the specification does not identify promoter regions associated with the claimed nucleic acid molecules. Further, in the absence of the function of SEQ ID NO: 4, undue experimentation would be required by one skilled in the art

Art Unit: 1638

to determine how to use additional sequences isolated by using the claimed nucleic acid molecule.

Appellants assert that the fourth, fifth and sixth Wands criteria focus on the nature of the invention, state of the art, and relative skill in the art, and argue that the invention relates to nucleic acid sequences, that the specification describes amino acid sequences derived from them, antibodies, constructs, methods related thereto, and that practitioners of the art are guided by resources that can be used to identify, confirm and introduce into other hosts, nucleic acid and amino acid sequences (Appeal Brief, paragraph bridging pages 15-16). However, the specification does not teach how one would use a transgenic host transformed with the claimed nucleic acid molecules. The specification does not teach how one skilled in the art would identify and confirm that a nucleic acid homologue has been isolated when the function of the open reading frame that SEQ ID NO: 4 belongs to has not been taught.

The seventh Wands criteria pertains to predictability of the art, and Appellants argue that the Examiner has not provide evidence why one skilled in the art would not be able to predict conservative substitutions or use the nucleic acid molecules in the disclosed uses (response, page 16, 1st full paragraph). However, again, the specification does not teach how one skilled in the art would use any nucleic acid molecules that have been isolated using the claimed nucleic acid molecules, since the function of SEQ ID NO: 4 is unknown. What trait is conferred to a transgenic plant into which SEQ ID NO: 4 has been introduced, for example? Further, the correct reading frame of SEQ ID NO: 4 cannot be confirmed in the absence of the remainder of the open reading frame.

Art Unit: 1638

The eighth criterion focuses on breadth of the claims, and Appellants argue that one of skill in the art is specifically guided by the disclosure to look to sequence identity to determine which species among those encompassed by the claimed genus possess the disclosed utility (Appeal Brief, page 16, 2nd full paragraph). It appears that Appellants are addressing those claimed molecules that comprise a nucleic acid molecule that share less than 100% sequence identity with SEQ ID NO: 4. However, one skilled in the art cannot determine if all of the claimed nucleic acid molecules share the same function as SEQ ID NO: 4, in the absence of knowledge of the function of SEQ ID NO: 4.

Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

Claims 1-2, 10, and 12-15 on appeal stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn towards any substantially purified nucleic acid molecule that encodes any plant protein comprising a nucleic acid sequence from SEQ ID NO: 4, wherein said substantially purified nucleic acid molecule is greater than 60% free from other molecules present in a natural mixture; or wherein said plant protein is a rice protein; or a substantially

Art Unit: 1638

purified nucleic acid molecule comprising a nucleic acid sequence from SEQ ID NO: 4 or complement thereof, wherein said substantially purified nucleic acid molecule is greater than 60% free from other molecules present in a natural mixture; or a substantially purified nucleic acid molecule comprising a nucleic acid sequence having between 100% and 90% sequence identity with a nucleic acid sequence of SEQ ID NO: 4 or complement thereof, wherein said substantially purified nucleic acid molecule is greater than 60% free from other molecules present in a natural mixture.

The specification discloses 43,701 nucleic acid sequences that are EST nucleic acid molecules (page 16, lines 1-6, sequence listing). The nucleic acid sequences were derived from rice cDNA libraries (page 33, lines 4-7; Example 1, pages 84-87). Here, the nucleic acid sequence of SEQ ID NO: 4 is the elected invention. The specification indicates that the disclosed ESTs can be used to acquire genes whose encoded proteins are involved in various plant processes (page 33, lines 4-26), or acquire promoters or cis-regulatory elements, or to generally obtain nucleic acid molecules from other organisms (page 34, line 1 to page 35, line 10). No particular use is disclosed for any of putative protein encoded by SEQ ID NO: 4.

A review of the full content of the specification indicates that SEQ ID NO: 4 is essential to the claimed invention. A review of the language of claim 1 indicates that the claim is drawn to a genus- any substantially purified nucleic acid molecule encoding any plant protein, or fragment thereof, comprising the nucleotide sequence in SEQ ID NO: 4, wherein said molecule is greater than 60% free from other molecules present in a natural mixture. Dependent claim 2 limits the plant protein to be from rice. Claim 10 also encompasses a broad genus- all substantially purified nucleic acid molecules comprising SEQ ID NO: 4 or complement thereof,

Art Unit: 1638

wherein said molecule is greater than 60% free from other molecules present in a natural mixture. A search indicates that the nucleotide sequence set forth in SEQ ID NO: 4 is novel and unobvious.

There is a single species explicitly disclosed- the nucleotide sequence consisting of SEQ ID NO: 4.

The disclosure of a single disclosed species may provide an adequate written description of a genus when the species disclosed is representative of the genus. The present claim encompasses full-length genes and cDNAs that are not further described. There is substantial variability among the species of DNAs encompassed within the scope of the claims because SEQ ID NO: 4 is only a fragment of a cDNA. When reviewing a claim that encompasses a widely varying genus, common attributes or features shared among species of the genus must be evaluated. In the case of a partial cDNA sequence that is claimed with open language (comprising), the genus encompasses a variety of subgenera with widely varying attributes. For example, a cDNA's principle attribute would include its complete coding region. A partial cDNA that does not include a disclosure of any complete open reading frame of which it would be a part, is not representative of the genus of cDNAs because no information regarding the coding capacity of any cDNA molecule is disclosed. Further, defining the cDNA in functional terms would not suffice in the absence of a disclosure of structural features or elements of a cDNA that would encode a protein having a stated function.

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which

Art Unit: 1638

features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Here, the specification discloses only a single common structural feature shared by members of the claimed genus, i.e., SEQ ID NO: 4. Since the claimed genus encompasses genes yet to be discovered, DNA constructs that encode fragments of proteins, etc., the disclosed structural feature does not “constitute a substantial portion” of the claimed genus. Therefore, the disclosure of SEQ ID NO: 4 does not provide an adequate written description of the claimed genus.

Weighing all factors, 1) partial structure of the DNAs that comprise SEQ ID NO: 4, 2) the breadth of the claims as reading on genes yet to be discovered in addition to numerous fusion constructs and cDNAs, 3) the lack of correlation between the structure and function of the genes; in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that Applicants were in possession of the genus of substantially purified nucleic acid molecules which comprise SEQ ID NO: 4.

Claim 12 is drawn to a genus- all substantially purified nucleic acid molecules comprising any nucleic acid sequence having between 100% and 90% sequence identity with SEQ ID NO: 4 or complement thereof, wherein said molecule is greater than 60% free from other molecules in a natural mixture. Claims 13-15 limit the substantially purified nucleic acid molecule of claim 12 to have between 100% and 95%, 100% and 98%, and 100% and 99% sequence identity to SEQ ID NO: 4. However, the only species encompassed by the claims that is described by the specification is the nucleotide sequence of SEQ ID NO: 4. All of the other species encompass nucleic acid sequences that differ from SEQ ID NO: 4. No function is

Art Unit: 1638

assigned to the amino acid sequence encoded by SEQ ID NO: 4. The specification has failed to correlate a function with the structures of substantially purified nucleic acid molecules sharing between 100% and 90% sequence identity with SEQ ID NO: 4.

Appellants' Arguments and Examiner's Response

Appellants argue that it is not proper basis to reject a claim for lack of written description because of the open language, "comprising," and that if it were, every "comprising" claim would be invalid for failing to describe every nuance of the claimed invention (Appeal Brief, paragraph bridging pages 17-18). However, Appellants have not been required to describe *every* nuance. Rather, the specification only describes a single species, the nucleotide sequence set forth in SEQ ID NO: 4.

Appellants argue that the application describes more than just SEQ ID NO: 4, for example gene sequences, corresponding sequences from other species, promoter sequences, plant homologue proteins (Appeal Brief, page 19, 1st full paragraph). However, none of these sequences are described in the specification. Appellants have not provided any full-length gene sequences. Nucleic acid sequences encoding plant homologue proteins are not described, especially given that the identity of the full-length protein encoded by the complete open-reading frame that comprises SEQ ID NO: 4 is not disclosed. The court in *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), held that "An adequate written description of a DNA... requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention". While Appellants are not required to disclose every species encompassed by a genus, the description of

Art Unit: 1638

a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. In the present situation, Appellants have provided only a disclosure of a wish to obtain gene sequences, homologues, and mutants comprising SEQ ID NO: 4 or sequences having 100% to 90% sequence identity to SEQ ID NO: 4.

Appellants cite the Federal Circuit decision of *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1321, 63 USPQ 2d. 1609, 1610 (Fed. Cir. 2002) in support, arguing that the court determined that “it may well be that various subsequences, mutations, and mixtures of those sequences are also described to one of skill in the art” (Appeal Brief, page 20, 1st full paragraph). However, in the patent considered in the *Enzo* decision, the deposited material corresponded exactly to one of the claimed products. The appeals court remanded the case to the district court to make findings on whether there was a correlation between the structure of the deposited material and the function of the variant material also claimed.

Appellants argue that they have disclosed a common structural feature, SEQ ID NO: 4, and that if a particular nucleic acid molecule contains SEQ ID NO: 4, then it is a member of the claimed genus (Appeal Brief, paragraph bridging pages 20-21). However, SEQ ID NO: 4 is not shared with nucleic acid molecules that comprise a sequence that has less than 100% identity to SEQ ID NO: 4, as claimed. Appellant argues that if a nucleic acid molecule contains a sequence that has 95% identity with SEQ ID NO: 4, then it is a member of the claimed genus (footnote on page 20). However, it is noted that the criteria for meeting the written description requirement is not limited to providing a means for distinguishing between molecules which fall within the claimed genus and molecules which fall outside the claimed genus. Rather, the requirement is

Art Unit: 1638

met by providing a showing that Appellants were, at the time the application was filed, in possession of the claimed invention. Providing a statement that the invention covers nucleic acid having 90-100% identity with SEQ ID NO: 1 is not equivalent to disclosing nucleic acids which fall within the claimed genus of nucleic acids. The specification does not describe any non-coding region of any gene that comprises SEQ ID NO: 4 or variant sequences that comprise SEQ ID NO: 4, or the functions of such genes or variants.

In response to the Examiner's previous response, indicating that the functional activity of SEQ ID NO: 4 is not correlated with the claimed genus of nucleic acid molecules because the functional activity of SEQ ID NO: 4 is not provided, Appellants argue that claims 10 and 12-15 do not recite that the nucleic acid molecule encodes a plant protein (Appeal Brief, page 21, 2nd full paragraph). However, nucleic acid molecules encoding proteins are encompassed by the claims. Further, Appellants themselves have argued that nucleic acid molecules comprising nucleic acid sequences having conservative variations or encoding amino acid sequences having conservative substitutions or plant homologue proteins are allegedly described (see Appeal Brief, page 19, 1st full paragraph).

For the above reasons, it is believed that the rejections should be sustained.

Art Unit: 1638

Respectfully submitted,



Ashwin Mehta
Primary Examiner
Art Unit 1638

May 12, 2005

Conferees



Amy Nelson, Ph.D.
Supervisory Patent Examiner
Art Unit 1638



Ardin Marschel
Supervisory Patent Examiner
Art Unit 1631

Lawrence M Lavin, Jr.
Patent Department E2NA
Monsanto Company
800 N Lindbergh Boulevard
St. Louis, MO 63167